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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	Possis Medical, Inc. 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA
Contact Person:	Mr. Mark Stenoien, Manager, Clinical & Regulatory Affairs 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA Phone: (763) 780-4555 Fax: (763) 780-2227 Email: mark.stenoien@possis.com
Date Prepared:	16-August-2005
Trade Name:	The AngioJet Xpeedior 120 Catheter
Classification Name and Number:	AngioJet Xpeedior 120 Catheter is a class II device per 21 CFR 870.5150 for peripheral thrombectomy and the Power Pulse Spray Ancillary Kit is a class II devices as defined by 21 CFR 870.1210 for infusion of Physician-specified fluids into the peripheral vasculature.
Product Code:	AngioJet Xpeedior 120 Catheter product code is DXE and 74 KRA.
Predicate Device(s):	The AngioJet 120 Catheter is substantially equivalent to the devices listed below: • The AngioJet Pulse Spray Kit and Xpeedior 120 Catheter (K040013.)
Device Description:	The AngioJet Xpeedior 120 Catheter is a single-use component of the AngioJet Rheolytic Thrombectomy System. The AngioJet System is intended for mechanical throbectomy removal. The Power Pulse Spray Ancillary Kit enables the AngioJet Xpeedior 120 Catheter to deliver a pulsed infusion of a physician-specified fluid to a local treatment area during a peripheral intervention.
Intended Use:	The AngioJet Xpeedior 120 Catheter is intended for use with the AngioJet System • in breaking apart and removing thrombus from infrainguinal peripheral arteries ≥3.0 mm in diameter; and/or • with the AngioJet Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.
Functional and Safety Testing:	The Xpeedior 120 Catheter is nearly the same device as identified K040013. Therefore, the testing listed in K040013 is sufficient to determine that the subject device is suitable for its intended use.
Conclusion:	Possis Medical, Inc. considers the Xpeedior 120 Catheter to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2005

Possis Medical, Inc.
c/o Mr. Mark Stenoien
Manager, Clinical & Regulatory Affairs
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K052256
AngioJet® Xpeedior® 120 Catheter
Regulation Number: 21 CFR 870.5150 and 870.1210
Regulation Name: Embolectomy Catheter and Continuous Flush Catheter
Regulatory Class: Class II (Two)
Product Code: DXE and KRA
Dated: August 16, 2005
Received: August 18, 2005

Dear Mr. Stenoien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volkmann

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Page

510(k) Number (if known): K052256

Device Name: AngioJet Xpeedior 120 Catheter

Indications For Use:

The AngioJet Xpeedior 120 Catheter is intended for use with the AngioJet System

- in breaking apart and removing thrombus from infrainguinal peripheral arteries ≥3.0 mm in diameter; and/or
- with the AngioJet Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

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